

what is claimed is:  
CLAIMS:

1. A process for the production of a peptide, the process comprising expressing in the milk of a transgenic non-human placental mammal a fusion protein comprising the peptide to be expressed linked to a fusion partner protein which is lysozyme.

2. A process as claimed in claim 1 which further comprises the steps of separating the fusion protein from the milk, and cleaving the fusion protein to yield the peptide.

3. A process as claimed in claim 1 or claim 2 wherein the lysozyme fusion partner is expressed at more than 5g/l in the milk of transgenic animals and is stable with carboxy terminal extensions.

4. A process as claimed in claim 3 wherein the lysozyme fusion partner is from a placental mammal, eg humans, cattle, sheep, goats, rabbits and rats.

5. A process as claimed in any one of claims 1 to 4 wherein the peptide is from 3 to 110, preferably 3 to 100 amino acids in length.

6. A process as claimed in any one of claims 1 to 5 wherein the peptide is one which requires post-translational modification in order to be biologically active, or improve *in vivo* half life, for example  $\alpha$ -amidation.

7. A process as claimed in claim 6 wherein the peptide is calcitonin, parathyroid hormone, glucagon, glucagon-like-peptide-1, a peptide with anti-microbial activity or a member of the general classes of peptide: magainins, histatins, protegrins and clavainins.

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8. A process as claimed in any one of claims 1 to 7 wherein the lysozyme fusion partner also includes a carboxy-terminus extension sequence, which serves as a linker between the lysozyme fusion partner and the peptide.

9. A process as claimed in claim 8 wherein the linker sequence is at least 10, 15 or preferably at least 20 amino acids in length.

10. A process as claimed in claim 9 wherein the linker has the sequence (gly-gly-gly-gly-ser)<sub>3</sub> (SEQ ID NO 1).

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11. A process as claimed in any one of claims 1 to 10 wherein the fusion protein also comprises a cleavage site between the fusion partner protein and peptide.

12. A process as claimed in claim 11 wherein the cleavage site is one which is cleaved by chemical or enzymatic means.

13. A process as claimed in claim 12 wherein the cleavage site includes a methionine residue and cyanogen bromide is used as the cleavage reagent.

14. A process as claimed in claim 11 wherein the cleavage site comprises a sequence of amino acids which includes a specific recognition site for enzymatic cleavage, and which does not occur anywhere else in the fusion protein.

15. A process as claimed in claim 14 wherein the cleavage site comprises the sequence Ile-Glu-Gly-Arg (SEQ ID NO. 2) or Asp-Asp-Asp-Lys (SEQ ID NO. 3).

16. A fusion protein comprising a peptide and a fusion partner protein which is lysozyme.

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17. A fusion protein comprising a fusion partner protein and a peptide joined by means of a flexible linker having the sequence (gly-gly-gly-gly-ser)<sub>3</sub>.

18. A fusion protein as claimed in claim 16 and further defined by any one or more of the feature in any one of claims 3 to 15.

19. A fusion protein as claimed in claim 17 and further defined by any one or more of the features in any one of claims 5, 6, 7 or 11 to 15.

20. An isolated or recombinant DNA molecule encoding a fusion protein, the DNA sequence comprising a coding sequence having a first segment encoding a fusion partner protein which is lysozyme coupled to a second segment encoding a peptide.

21. A DNA molecule as claimed in claim 20 which further comprises one or more control sequences, operatively linked to the coding sequence, which enables the coding sequence to be expressed in the milk of a transgenic non-human placental animal.

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22. A DNA molecule as claimed in claim 21 which includes a promoter, preferably one which drives expression of a protein which is naturally found in the milk of a mammal.

23. A DNA molecule as claimed in claim 21 or claim 22 which includes a protein leader sequence.

24. A DNA molecule as claimed in any one of claims 20 to 23 which further comprises a sequence encoding a linker sequence as defined in any one of claims 8 to 10.

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25. A DNA molecule as claimed in any one of claims 20 to 24 which further comprises a sequence encoding a cleavage site as defined in any one of claims 11 to 15.

26. A vector comprising a DNA molecule as defined in any one of claims 20 to 25.

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27. A host cell transformed with a vector as defined in claim 26, preferably a mammalian cell.

28. A transgenic non-human placental mammal whose genome incorporates a DNA molecule comprising a coding sequence having a first segment encoding a fusion partner protein which is lysozyme coupled to a second segment encoding a peptide.

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29. A transgenic mammal as claimed in claim 28 which is a cow, a sheep, a goat, a rabbit, a mouse or a pig.

30. A composition comprising a fusion protein as defined in any one of claims 16 to 19.

31. A composition as defined in claim 30 which is milk isolated from a transgenic non-human placental mammal

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